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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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HEWLETT PACKARD COMPANY
P O BOX 272400, 3404 E. HARMONY ROAD
INTELLECTUAL PROPERTY ADMINISTRATION
FORT COLLINS, CO 80527-2400

EXAMINER

DIRAMIO, JACQUELINE A

ART UNIT	PAPER NUMBER
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1641

NOTIFICATION DATE	DELIVERY MODE
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10/08/2008

ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

JERRY.SHORMA@HP.COM
mkraft@hp.com
ipa.mail@hp.com

Office Action Summary	Application No. 10/762,784	Applicant(s) CHILDERS ET AL.	
	Examiner JACQUELINE DIRAMIO	Art Unit 1641	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 19 June 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1 and 3 - 20 is/are pending in the application.
- 4a) Of the above claim(s) 11-17 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,3-10 and 18-20 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 22 January 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Status of the Claims

Applicant's amendments to claims 1 and 18 are acknowledged, as well as the cancellation of claim 2.

Currently, claims 1, 3 – 10, and 18 – 20 are pending and under examination. Claims 11 – 17 are acknowledged as withdrawn as drawn to a non-elected invention.

Withdrawn Objections

The previous objection to the drawings is withdrawn in view of Applicant's amendment filed June 19, 2008.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1, 3, 4, 6, 7, and 18 – 20 are rejected under 35 U.S.C. 102(e) as being anticipated by Groll (US 2005/0019953).

Groll teaches a self-calibrating disposable blood test strip (device) comprising:
a substrate configured for carrying a chemical reagent; and

circuitry formed on the substrate, the circuitry comprising:

a measurement (sensor) portion associated with the chemical reagent to enable measurement of at least one of a presence and a concentration of a blood analyte;

an information storage portion configured to store information indicative of at least one property of the chemical reagent and other information for calibrating operation of a meter to accurately measure and monitor a test of the blood analyte; and

an input and output arrangement formed on the substrate and in electrical communication with the information storage portion to enable the meter to access the chemical reagent information and the other calibration information from the information storage portion (see Figures 1-4 and 10-15; and paragraphs [0010], [0011], [0014], [0035], [0036], [0038], [0039], [0041], [0047], [0061], [0064]-[0070], [0075]-[0084], and [0094]).

With respect to Applicant's claim 3, the information storage portion is electrically connected to a portion of the measurement portion of the circuitry, and includes at least one electrically conductive element having an electrical characteristic that is indicative of the property of the chemical reagent (see paragraph [0014]).

With respect to Applicant's claims 4, 6, and 19, the at least one electrically conductive element comprises a plurality electrically conductive elements wherein each element is configured to be physically altered, such as via etching, and the number of altered elements produces an electrical characteristic that is indicative of the property of

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the chemical reagent (see paragraphs [0014], [0039], [0041], [0042], [0045], and [0075]-[0084]).

With respect to Applicant's claim 7, the test device can comprise a set of test devices with the information storage portion of each test device storing substantially the same information (see paragraphs [0012], [0066] and [0070]).

With respect to Applicant's claim 18, the limitations of this claim are discussed above with respect to claim 1.

With respect to Applicant's claim 20, the information storage portion is inseparable from the disposable test strip (see paragraph [0065]).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claim 5 is rejected under 35 U.S.C. 103(a) as being unpatentable over Groll (US 2005/0019953) in view of Ward (US 5,410,504).

The Groll reference, which was discussed in the 102(e) rejection above, fails to teach that the device uses impedance, wherein the electrically conductive elements of the information storage portion are either a plurality of inductors arranged in series or a plurality of capacitors arranged generally in parallel.

Ward teaches a method of constructing a memory on a semiconductor substrate from a plurality of capacitor elements organized in a plurality of rows and columns, i.e. in parallel. The capacitor array may be used for storing information, such as a ROM. Each capacitor is used to store one bit of information, wherein a capacitor storing a "1" will have a different capacitance than a capacitor storing a "0" (see Abstract; column 1, lines 63-68; column 2, lines 1-68; and column 3, lines 1-30).

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to include with the device of Groll an array of capacitors arranged in parallel as taught by Ward because Ward teaches the benefit of creating a parallel capacitor array on a semiconductor substrate in order to create a memory that can be used for storing information, such as a ROM, wherein each capacitor is used to store one bit of information.

Claims 8 – 10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Groll (US 2005/0019953) in view of Mandecki (US 2002/0006673).

Groll further fails to teach that the circuitry of the substrate of the device comprises a semiconductor portion and a non-volatile memory, wherein an electrical signal generator external to the device is configured to send an electrical signal to the non-volatile memory to cause storage of the information in the information storage portion.

Mandecki teaches transponders for use in methods of detecting biomolecules in a sample, wherein the transponders comprise a solid phase, a reagent or biomolecule binding element, and an index number or memory element that is electronically encoded on the transponder. The index number can be unique to each solid phase, and is retrievable by a scanner device at any time during an assay. The index number can relate to the time and date on which the assay was performed, the patient's name, a code identifying the type of assay, catalog numbers of reagents used in the assay, or data describing the progress of the assay. The memory element can be encoded by a user just before, during or after a biological material is deposited on the surface of the transponder. The memory element is encoded with data sent by electromagnetic waves from a remote scanner read/write device, wherein the scanner read/write device further receives the encoded data transmitted by the transponder (see Abstract; and paragraphs [0007], [0009], [0021], [0027], [0031] and [0032]).

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to include with the device of Groll a memory element, wherein an external signal generator, i.e. scanner read/write device, is configured to send an electrical signal to the memory element to cause storage of information, as

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taught by Mandecki because Mandecki teaches the benefit of including a memory element on a transponder or solid phase device for detecting biomolecules in a sample, wherein the memory element can be encoded by an external scanner read/write device, in order to allow for encoding of the memory element by a user just before, during or after a biological material is deposited on the surface of the transponder. This encoding of the memory element allows for information to be stored within the transponder device for later retrieval, wherein the information can relate to the time and date on which the assay was performed, the patient's name, a code identifying the type of assay, catalog numbers of reagents used in the assay, or data describing the progress of the assay.

Response to Arguments

Applicant's arguments filed June 19, 2008 have been fully considered but they are not persuasive. Applicant argues (see p8-10) that the Groll reference (US 2005/0019953), which was used under 35 U.S.C. 102(e) for rejecting and anticipating Applicant's claims 1-4, 6, 7, and 18-20, fails to teach Applicant's amendment to independent claims 1 and 18 requiring "no other source of calibration information separate from the information storage portion on the disposable blood test device [to be] used for calibration of the meter." Further, Applicant argues that the test strip of Groll fails to include the calibration information on the test strip itself. However, these arguments are not found persuasive.

The Groll reference, which is used in the 102(e) rejection above, teaches a self-calibrating disposable blood test device comprising:

a substrate configured for carrying a chemical reagent; and
circuitry formed on the substrate, the circuitry comprising:
a measurement (sensor) portion associated with the chemical reagent to enable measurement of at least one of a presence and a concentration of a blood analyte;
an information storage portion configured to store information indicative of at least one property of the chemical reagent and other information for calibrating operation of a meter to accurately measure and monitor a test of the blood analyte; and
an input and output arrangement formed on the substrate and in electrical communication with the information storage portion to enable the meter to access the chemical reagent information and the other calibration information from the information storage portion (see Figures 1-4 and 10-15; and paragraphs [0010], [0011], [0014], [0035], [0036], [0038], [0039], [0041], [0047], [0061], [0064]-[0070], [0075]-[0084], and [0094]). In particular, the information storage portion of Groll provides encoded information directly onto the test strip device, wherein the encoded information includes calibration family information, such as the property or type of chemical reagent provided on the test strip device (see paragraphs [0061] and [0066]). Therefore, the test strip device of Groll does in fact include the calibration information directly on the test strip device itself.

With respect to Applicant's amendment to claims 1 and 18 requiring "no other source of calibration information separate from the information storage portion on the disposable blood test device [to be] used for calibration of the meter," this amendment

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recites an **intended use** of a claimed device. A recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. In this case, the test strip device of Groll includes all of the structural elements of Applicant's claimed device including: (1) the substrate; and (2) the circuitry, wherein the circuitry comprises: (a) a sensor/measurement portion; (b) an information storage portion; and (c) input and output arrangements formed on the substrate (see Figures 1-4 and 10-15; and paragraphs [0010], [0011], [0014], [0035], [0036], [0038], [0039], [0041], [0047], [0061], [0064]-[0070], [0075]-[0084], and [0094]). Therefore, because the device of Groll includes all of the required and recited structural elements, the device of Groll is capable of performing the intended use and thus, meets the claim. Further, the provided "ROM key" of Groll, which might be considered an "other source of calibration information," is not a necessary source of information required "for calibration of the meter." The "ROM" key is merely used for verifying that the calibration information encoded on the test strip device matches the calibration information included on the "ROM" key (see paragraphs [0061]-[0070]). This "ROM" key comprises a part of the intended use of the device of Groll. However, because the device of Groll includes all of the required structural elements of Applicant's claimed device, the device of Groll is capable of performing the intended use and again, meets the claim.

Conclusion

No claims are allowed.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to JACQUELINE DIRAMIO whose telephone number is (571)272-8785. The examiner can normally be reached on M-F 9-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mark Shibuya can be reached on 571-272-0806. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Jacqueline DiRamio/
Examiner, Art Unit 1641

/Mark L. Shibuya, Ph.D./
Supervisory Patent Examiner, Art Unit 1641